

Midwest Sterilization Corporation comments to Pre-Panel Outreach Meeting – June 11, 2020

Appendix A. Questions to Small Entity Representatives (SERs)

EPA Objectives for the Pre-Panel Outreach Meeting

- Understand facility/company practices of small business across the ethylene oxide (EtO) commercial sterilization and fumigation industry
- Gain clear understanding of processes in the ethylene oxide (EtO) commercial sterilization and fumigation industry

The input and feedback EPA will receive on these questions will be used to inform the materials discussed with the SERs at the Small Business Advocacy Review (SBAR) Panel Outreach meeting. The feedback provided from these questions will be used to inform our proposal of control strategies to achieve emission reductions of EtO, and these potential control strategies will be presented to the SERs as part of the SBAR Panel Outreach meeting.

Overarching Topics/Questions for Small Business

Question: How do you anticipate the potential regulations would affect your business? For example, would this require the purchase of any unique equipment or the hiring of additional staff?

MSC: This question is difficult to answer without more information as to what the regulations will require. A general answer would be that we expect the regulations to have multiple effects. Increased regulations will require additional equipment, record keeping, administrative, maintenance, etc. responsibilities. All of these responsibilities will add additional routine labor costs.

Question: What rule flexibilities do you believe may reduce small entity burden? Can these flexibilities be structured in a way to better provide assistance to small entities in reducing potential burdens? Are there any flexibilities that would help your business, specifically?

MSC: We think a better question is what potential control strategies will be too taxing for small entities or for facilities of a certain size. For instance we are a small entity, however, we operate large scale facilities. Specifically controlling fugitive emissions from large warehouse style facilities can be unfeasible from a technical standpoint as well as an economical standpoint.

Question: Do you anticipate any significant issues or circumstances not addressed in the materials provided?

MSC: Yes, the control of fugitive air from large sterilizers is something that is not always feasible from a technical standpoint and even less feasible from an economical standpoint.

Question: If you serve a niche market or are in a unique geographical location, do you anticipate any specific burdens and/or issues resulting from the potential rulemaking?

MSC: N/A

Question: Do your answers to any of the above questions differ depending on the start date or stringency level of the standards?

MSC: The start date will not change our answers, however, the stringency level will. That being said, we are not provided with enough information here for us to provide a more detailed answer. For example, increasing control efficiencies from 99% to 99.9% may seem like a small increase, however, can be a very

complex process; increases in control efficiencies almost always require additional equipment and sometimes require you to replace the existing equipment all together. Certain performance efficiencies may also exceed certain technical and economical limits.

Question: Do you believe that additional lead time would be necessary for you to comply with new standards?

MSC: Yes, once new regulations are written there will be an increased demand for the equipment, consultants, engineers, and everything else necessary to meet the new requirements. Companies with larger pocketbooks will be able to pay higher expedite fees for their orders causing the orders for smaller companies to get delayed and pushed back.

Question: Are there any sector-unique business or competitive issues that we should understand? Are there any business or competitive issues associated with your business, specifically?

MSC: Can you be more specific with this question or provide an example?

Question: Are there any subcategories that you would recommend for your industry (e.g., product type, sterilizer size, EtO usage, etc.)? If so, please identify them and document the basis for your recommendation.

MSC: N/A

Question: Do you anticipate any unique legal, administrative, or record-keeping burdens associated with your compliance?

MSC: Yes, any additional equipment upgrades to meet new regulations will require maintenance, administrative, and record keeping increases which will all come with increased operating costs. Increased record keeping requirements alone will come with additional operating costs.

Question: Number of employees (at each of your facilities and/or business wide)?

MSC: Approximately 75 employees at our Missouri facility and approximately 170 employees at our Texas facility with approximately 50 of those employees working through a placement agency.

Question: What is the relative capital and labor intensity of production at small facilities, e.g., are production costs primarily labor or capital?

MSC: Costs are a mix with the primary being capital for our facilities.

Question: Profit or sales information, if you are willing to share (these data may be claimed as CBI).

MSC: N/A

Question: What are your business' plans for the future? Include expansions, new facilities, expansion into new sterilization or fumigation methods, etc.?

MSC: Expansion plans are very difficult to determine without knowing what future regulations will require. However, we currently have had difficulty meeting customer capacity requirements and have had to turn away many customers recently, potentially causing shortages of medical equipment. Some customers have even reported going out of business. So, if feasible, MSC is willing to install additional sterilizers and or open up future facilities to prevent medical device shortages. We just have to know what the new regulations will require so we know if it is feasible to continue expanding our operations.

Question: Would the potential control strategies increase your labor costs (see list in the presentation slides)?

MSC: Yes, any potential control strategies will require additional preventative maintenance, record keeping, and administrative costs which will increase our labor costs. It is not possible to give specific details until more details about the regulations are released, however, we estimate the control of fugitive emissions to pose the most significant labor and material costs potentially to a point where they are not economically feasible.

Question: Are the potential control strategies technically feasible for your facilities? Are they economically feasible for small businesses in this industry? Might they impose more of a disadvantage to small businesses than larger ones? If so, what type of control options might be feasible for small businesses?

MSC: This question cannot be completely answered until we are given more information, such as the emissions control efficiency of each potential control strategy, etc. A lot of the Potential Control Strategies are still fairly vague. For example, with "Reinstating CEV Control Requirement" you mention several options; the first one – venting emissions to an APCD – does not give an efficiency rating for the APCD. Implementing a CEV control requirement of 99% may be feasible, however, a control efficiency of 99.9% or more may become very challenging and may not be technically and economically feasible for our facilities. The next option of implementing a limit on the EtO concentration in the sterilizer before opening the chamber door does not define what that limit is. Certain limits may be economically and technically feasible and some may not. The third option of using interlocks on chambers not allowing them to open until a certain concentration is met does not define what this limit is. Certain limits may be economically and technically feasible and some may not. So, it is difficult to say what exactly is technically and economically feasible for most of these options, including the option of "Increasing control device efficiencies and removal efficiencies" since we do not know the specifics of these efficiencies. The control strategy posing the most potential impacts is the control of fugitive emissions. Pollution control equipment is sized off of many factors, however, one primary factor is airflow ratings. If you are trying to send all the air in a facility to a piece of control equipment the size of this piece of equipment will have to be very substantial. Our facilities exhaust hundreds of thousands of cfm of air. The size of the pollution control equipment to handle this much air is not something that is technically or economically feasible for our facilities. Another factor to consider is the current control technology is not designed to handle such low concentrations of ethylene oxide as you would find in a warehouse. So, trying to capture this air with a piece of pollution control equipment would only yield minor results, if any. Some small businesses may not be able to weather the economic impacts of installing additional control equipment.

Question: Would the potential control strategies interrupt operations at your facilities and/or reduce sales revenue? For example, would you have to shut down a facility to add controls or add time/steps to your process?

MSC: Yes, anytime a piece of emissions control equipment is added or modified the facility will have to shut down. This is because emissions streams would have to be turned off (meaning sterilization chambers/aeration rooms/etc. must finish processing and then be shut down) to connect these streams to the pieces of control equipment. The system must then be started back up and brought up to certain operating conditions, this process will vary depending on the type of equipment and the size of the equipment. Once the system is operating it will have to be validated to ensure all components are operating sufficiently and any issues are corrected. Once the system is operating sufficiently the emissions streams will have to be reactivated so the equipment performance can be determined. This entire process may take up to a few weeks. Our facilities operate 24 hours a day, 7 days a week, 365 days a year so any shut down in operations effects the amount of medical products we can process each and every year.

Question: Do you currently conduct any work or operating practices (other than the use of an air pollution control device) that would have an impact on EtO emitted from your facilities? If yes, please explain.

MSC: Yes, we develop sterilization cycles to get as much ethylene oxide as possible out of the products prior to ending the sterilization cycle.

Question: Are there other regulations that have been issued since your business started that imposed impacts on your operations (e.g., OSHA rules, rules from other agencies that regulate chemicals like DHS, etc.)? How have small businesses dealt with past regulatory impacts?

MSC: OSHA has standards to what levels of ethylene oxide our employees can be exposed to which have been modified since we have been in business. We have modified warehouse procedures, cycles, air flow, etc. to meet these standards.

Question: Are there other potential control strategies that you are aware of that should be considered in a proposed rulemaking?

MSC: N/A

Technical Topics/Questions for Small Business

EtO Drum Storage

Question: Is there a standard size drum or cylinder that is typically used for commercial sterilization or fumigation at small businesses?

MSC: We use two types of drums, drums which sit on the scale (operating cylinders) and drums which the ethylene oxide ships in (shipping containers). The size of operating cylinders can vary; however, shipping containers are consistently 400 pounds for us and also from what we have seen for other companies with multiple pallet sterilizers. Some much smaller sterilizers (room or table top size) may use smaller sizes, however, we are not familiar with them.

Question: What is the range of annual EtO usage at small businesses?

MSC: Small businesses can see a range of anything that large businesses can. The usage depends on the amount of sterilizers and what types of sterilizer chambers they are. Our facilities use more ethylene oxide than a lot of the facilities operated by larger businesses because we operate larger sterilization facilities.

Question: Do your facilities typically conduct leak monitoring? What leak monitoring is conducted on drums and cylinders? What leak monitoring is conducted on lines and connections to the sterilizer/fumigation chamber?

MSC: Yes, at our facilities vacuum leak tests are performed back to the ethylene oxide storage room during routine production cycles. Vacuum leak tests are also performed anytime maintenance is performed on a piece of chamber equipment which could cause a leak. Extended vacuum leak tests are also performed quarterly in every chamber. Lines which are not included during these leak tests are visually inspected for leaks.

Question: Are there dedicated rooms for the storage of the drums/cylinders?

MSC: There are dedicated rooms at our facilities for ethylene oxide storage and distribution

Sterilization Chamber

Question: Are there any differences in the sterilizer chamber equipment in use at small businesses versus other companies?

MSC: There are different types of sterilizers, however, this is not business size dependent. Small and large sterilizers may use the same types of equipment, typically just different amounts of equipment and amounts of locations. Some small businesses have large scale facilities, just not very many employees or very many locations like the larger businesses.

Question: Can you describe the vacuum cycles that are used at your facilities, including physical equipment utilized for the vacuum cycle?

MSC: Our facilities use Travaini liquid ring vacuum pumps as primary pumps and Tuthill rotary positive displacement blowers for booster pumps. Our facilities use a large variety of cycles with vacuums levels from anywhere between slightly below atmospheric and 1.0 InHgA. All cycles operate below atmospheric pressure.

Question: How many chambers are in EtO service at any given time?

MSC: What are you referring to as EtO service? At our facilities all of our chambers can be running at any given time, however, they will be in various stages of the cycle. Some may be just starting a cycle, with others in a dwell period, other in wash phases, and others being unloaded.

Question: Do any companies pressure test their sterilization chambers for leaks, and how often does this occur? Are any other leak tests performed?

MSC: Yes, at our facilities vacuum leak tests are performed back to the ethylene oxide storage room during routine production cycles. Vacuum and pressure leak tests are also performed anytime maintenance is performed on a piece of chamber equipment which could cause a leak. Extended vacuum and pressure leak tests are also performed quarterly in every chamber. Lines which are not included during these leak tests are visually inspected for leaks.

Aeration Room

Question: Are there differences in the aeration equipment used at small business facilities? What type of aeration unit is most commonly used, e.g., aeration room, aeration cell, aeration chamber?

MSC: Small businesses can see a range of anything that large businesses can. The usage depends on the amount of sterilizers and what types of sterilization chambers they are using. As well as what type of aeration they were originally set up using as switching to a new form of aeration will have extensive technical impacts which may not be feasible because of their current building design and may not be economically feasible because they would have to shut down operations to modify the aeration cells

Question: Are there any instances where products are not immediately moved to aeration after sterilization? If so, please elaborate.

MSC: N/A

Question: Is the aeration unit monitored for pressure drop (or facial velocity) to verify the inflow of air?

MSC: Yes, the exhaust velocity of the aeration rooms is measured at our facilities

Question: Do any small business use “accelerated degassing cells” for aeration? If so, please elaborate on how and why they are used.

MSC: Can you define accelerated degassing cells?

Chamber Exhaust

Question: Are chamber exhaust vents typically sent to a control device at small businesses, or is it more typical to vent to atmosphere?

MSC: This is independent of business size, and simply depends on the equipment the business uses, if it is feasible, and their preference. Our chamber exhaust goes to a control device at each of our facilities.

Question: Is that control device also used to control other emission sources at the facility (e.g., sterilizer chamber vents or aeration room vents), or is the control device dedicated to the chamber exhaust?

MSC: At one of our facilities it is and at the other facility it isn't currently. We are working to install new equipment and then each facility will have the chamber exhaust going to a wet scrubber which also acts as a polishing system for already treated SCV emissions.

Warehouse Storage

Question: Have small businesses typically conducted measurements on the residual EtO remaining in the sterilized product following aeration?

MSC: Medical device manufactures are responsible for following FDA guidelines and ensuring that products meet certain ethylene oxide residual limits before they reach the patient. Contract sterilizers cannot send product to laboratories for ethylene oxide residual analysis since they do not own the product. So if a small business is the manufacture of the product they are sterilizing then they may have, however, this is not a requirement since sterilizers do not always own the products and this is a responsibility of the manufacturers of the products.

Work Area Air

Question: Is the room air from the areas listed below at the facility sent to a control device?

- Room air surrounding the EtO tanks

MSC: Not at our facilities

- Room air surrounding the sterilizer chambers

MSC: Not at our facilities

- If Aeration cells or Aeration chambers are used, room air surrounding these aeration units

MSC: N/A

- Warehouse area

MSC: Not at our facilities except that makeup air for aeration rooms comes from the warehouse and that air goes through the aeration room control device.

- Other?

MSC: Only SCV, CEV, ARVs (including the air mentioned above) are currently sent to control devices at our facilities

Question: During the unloading of material from the sterilization chambers, what is the typical concentration of EtO observed within the in work/room areas?

MSC: N/A

Question: Do any companies have facilities with requirements to control these room air emissions?

MSC: N/A

Question: What mechanisms are in place at your facilities to ensure that the areas in EtO service are under negative pressure, if applicable?

MSC: N/A

Control Equipment

- Capital and annual costs for range of sizes, flowrates, and EtO concentrations.
- Typical engineering and installation costs.
- Parametric monitoring of controls and Parameter set points (pH, liquor level, temperature, pressure drop, etc.)

MSC: There is not enough information listed here to provide adequate cost information. Costs for all of the listed equipment/services will vary greatly with different projects. What we can say is that we have many questions about and potentially think the cost information listed in Appendix D. Preliminary Draft Cost Estimates for Potential Control Strategies is fairly misleading. For example, you list various types of control equipment pricing without even stating all process specifications, loading rates, and performance efficiencies. You also do not provide a list of supporting equipment, preventative maintenance, recordkeeping, administration, installation, and other associated tasks/costs. These can range drastically and can sometimes cost more than the control devices themselves. For example, we recently installed a wet scrubber system at our Jackson facility. This wet scrubber controls a combined emissions stream coming from our other wet scrubber system and our chamber exhaust vent system. The cost for just this scrubbing equipment from the manufacturer was a certain amount, however, this was not the cost to make this system functional. The total cost of the system was approximately three times the cost of the scrubber alone. So just because a piece of control equipment costs a certain amount does not mean that is the total amount for the system to be completed.

Performance Testing and Monitoring

Question: Is in-plant EtO concentration monitoring for room areas conducted, and what measurement techniques are used, e.g., gas chromatography (GC), lower explosive limit (LEL) monitors, etc.?

- Is the air within the EtO storage area monitored for EtO concentration?

MSC: Yes, gas chromatography, oxygen monitoring, and LEL monitoring are performed at our facilities

- Is the room air surrounding the sterilizer chambers monitored for EtO concentration?

MSC: Yes, gas chromatography and LEL monitoring are performed at our facilities

- If Aeration cells or Aeration chambers are used, is the room air surrounding these aeration units monitored for EtO concentration?

MSC: N/A

- Are warehouse areas at small businesses typically monitored for EtO concentration?

MSC: Gas chromatography is performed at our facilities, however, we do not know if this is a standard practice for small businesses.

Question: Has any performance testing been conducted outside of Subpart O? (State, Local, CD, Vendor Guarantee)

MSC: N/A

Question: Post-control EtO monitoring (measurement of stack EtO concentration using CEMs), what is the detection limit of the monitor, and capital and annual cost?

MSC: We do not have one of these systems in place, however, we have been quoted approximately \$150,000 for a CEMS system. This does not include labor, installation pieces, maintenance, sampling lines, and anything else necessary to make this system operational